K070123

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

Submitter Name:	Dornier MedTech America, Inc.
Submitter Address:	1155 Roberts Blvd. Kennesaw, GA 30144
Contact Person:	Tim Thomas, Vice President Regulatory/ Quality/ Clinical
Phone Number:	770-514-6163
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Establishment Registration Number:	1037955
Date Prepared:	January 12, 2007
Device Trade Name(s):	TCA 5R / 5S
Device Common Name:	Fluoroscopic Imaging System or Mobile C-Arm
Classification Name:	System, x-ray, fluoroscopic, image-intensified (JAA) System, x-ray, mobile (IZL)
Device Classification:	II (21 CFR Sec. 892.1650 and 892.1720) (Image-intensified fluoroscopic x-ray system / Mobile x-ray system)
Predicate Device(s):	K992103 – Wuestec Medical Inc. (C-Quest) K002198 - Fluoroscan Imaging Systems (Hologic) (FlouroScan Profile)
General Device Description:	The *TCA 5R / 5S* are mobile C-arms specifically designed for x-ray imaging
Intended Use:	The *TCA 5R / 5S* C-arm systems are designed for x-ray examinations, and in particular, for radioscopy, radiography, and diagnosis dedicated to: traumatology, pediatrics, simple interventional radiology, pacemaker implantation, operating room procedures, intensive care, and respiratory and skeleton procedures.
Technological Characteristics:	The *TCA 5R / 5S* consists of two mobile units: a C-Arm and a Monitor Trolley which holds one or two

MAR 0 9 2007

	monitors, an image processing system and possible accessories. The C-Arm stand supports the high-voltage generator, x-ray controls, and the "C" shaped arm which supports the x-ray tube and the image intensifier. The C-Arm is designed to move in various directions to allow for proper positioning with the patient based on the procedure. Additional technological characteristics are provided in Section 10 (Device Description) and Section 11 (Substantial Equivalence)
Performance Data:	The *TCA 5R / 5S* comply with the applicable performance standards listed in Section 8 (Declaration of Conformity)
Conclusion:	Based on a comparison to the predicate device determined to be substantially equivalent through the 510(k) premarket notification process, Dornier MedTech America, Inc., concludes that the *TCA 5R / 5S are as safe, as effective,* and performs as well as other legally marketed C-arm devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Tim Thomas
Vice President, Quality / Regulatory / Clinical
Dornier MedTech America, Inc.
1155 Roberts Blvd.
KENNESAW GA 30144

MAR 0 9 2007

Re: K070123
Trade/Device Name: TCA 5R / 5S
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: JAA and IZL
Dated: January 12, 2007
Received: January 17, 2007

Dear Mr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K070123

Device Name: TCA 5R / 5S

Indications for Use:

The TCA 5R / 5S C-arm systems are designed for x-ray examinations, and in particular, for radioscopy, radiography, and diagnosis dedicated to: traumatology, pediatrics, simple interventional radiology, pacemaker implantation, operating room procedures, intensive care, and respiratory and skeleton procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

David G. Hyun

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070123